REMARKS

Claims 58-61 and 63-66 are pending in the subject application. No claims have been added, canceled, or amended herein. Accordingly, claims 58-61 and 63-66 are still pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's outstanding rejections have been overcome and respectfully request that the Examiner reconsider and withdraw same.

Double Patenting Rejection

The Examiner rejected claims 58-61 and 63-66 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 53, 59, 60, 65, 71, 72, and 77-82 of U.S. Serial No. 09/017,976, now claims 1-12 of U.S. Patent No. 6,500,627, ("the '627 patent) for the reasons of record.

In response, applicants respectfully traverse.

Claims 58-61 provide a method for predicting pregnancy outcome in a subject. Specifically, these claims provide a method comprising a step of detecting the *ratio* of EMPI-hCG to intact hCG in a sample, wherein a *ratio greater than 1* indicates a positive pregnancy outcome, and a *ratio less than 1* indicates a negative pregnancy outcome. Claims 63-66 provide a kit for predicting pregnancy outcome comprising four particular antibodies and reagents permitting binding between the antibodies and their respective antigens. These four antibodies are exemplified by B152, B207, B109 and B108.

To establish a case of obviousness-type double patenting with respect to the '627 patent over the instant application, the Examiner must demonstrate three things with respect to each claim of the subject application. First, the issued claims of the '627 patent, in view of ordinary skill, must teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the '627 patent claims at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed. It is stressed that in an obviousness-type double patenting rejection, it is the *claims* of the cited patent which must render the pending claims obvious.

Applicants maintain that the '627 patent claims fail to support a case of obviousness-type double patenting because the '627 patent claims fail to teach or suggest each element of the pending claims. Specifically, the claims of the '627 patent fail to teach or suggest the step of determining a ratio of EPMI-hCG to intact hCG in a sample wherein a *ratio of 1* is the number above which a positive pregnancy outcome is indicated. This step is recited in claims 58-61 of the instant application. Furthermore, the claims of the '627 patent also fail to teach or suggest combining the four antibodies and reagents present in the kit of claims 63-66 to form a kit, let alone a kit for predicting pregnancy outcome.

In view of the above remarks, applicants maintain that claims 58-61 and 63-66 are not obvious over the claims of the '627 patent, and therefore should not be rejected under the judicially created doctrine of obviousness-type double patenting.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 63-66 under 35 U.S.C. §103(a) as allegedly unpatentable over Cole et al. (U.S. Patent No. 6,429,018)("Cole"), in view of Birken et al. (Endocrinology, 1993)("Birken"), and in further view of Foster et al. (U.S. Patent no. 4,444,879).

In response, applicants respectfully traverse.

Claims 63-66 are discussed above.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, must teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Applicants maintain that the cited references fail to support a *prima facie* case of obviousness because the references do not provide any motivation for combining the teachings therein to practice the claimed invention. Specifically, Cole teaches a method for prenatal screening for nicked hCG in Down's Syndrome cases in a urine sample. Birken teaches a two-site immunoradiometric assay used to evaluate early pregnancy losses by separating nicked from intact non-nicked hCG as well as from the β-core fragment. Foster teaches incorporating labels, antibodies, reagents and kits into a kit format. Cole, Birken and Foster, in combination, fail to provide motivation to combine the teachings of all three references to

form the claimed kit and the Examiner has failed to prove otherwise. That is, even if the references, only when combined, taught all antibodies and reagents of the instant kits (which applicants do not concede), this alone is not enough to render the kits obvious. Rather, the references must also provide a motivation to combine these antibodies and reagents. Applicants maintain that no such motive exists.

In view of the above remarks, applicants maintain that claims 63-66 satisfy the requirements of 35 U.S.C. §103(a).

Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the $395.00 RCE filing fee and $225.00 extension fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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